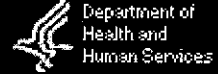


Exhibit C

<http://www.cfsan.fda.gov/~dms/cos-pb.html>

**U.S. Food and Drug Administration****CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**[FDA Home Page](#) | [CFSAN Home](#) | [Search/Subject Index](#) | [Q & A](#) | [Help](#)**CFSAN/Office of Cosmetics and Colors****December 27, 2007**

Lipstick and Lead: Questions and Answers

- [What is FDA's legal authority over cosmetics?](#)
- [Has FDA been aware of concerns about lead in lipstick?](#)
- [Has FDA published tolerance levels for lead in lipstick?](#)
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The Food and Drug Administration (FDA) has received a number of inquiries regarding reports of levels of lead in lipstick. The following information is drawn from responses to those inquiries.

What is FDA's legal authority over cosmetics?

FDA regulates cosmetics under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Act does not subject cosmetics to pre-market approval by FDA, with the exception of most color additives. It does, however, require that cosmetics marketed in interstate commerce be safe when used as directed in the labeling or under customary conditions of use. The FD&C Act subjects all color additives (other than coal-tar hair dyes) used in FDA-regulated products, including those used in lipstick, to pre-market approval. The listing regulation for each approved color additive includes limits for trace levels of heavy metal contaminants, if appropriate. FDA can and does take action against firms and individuals who violate the law, as determined by public health priorities and resources. To learn more on this subject, please refer to [FDA Authority Over Cosmetics](#).

Has FDA been aware of concerns about lead in lipstick?

Reports about lead in lipstick are not new. In the 1990s, reports of analytical results from a commercial testing laboratory suggested that traces of lead in lipstick might be of concern. Subsequent evaluation by FDA of that laboratory's test results determined that an unvalidated and inappropriate testing method had been used. FDA's analyses did not detect levels of lead that would be considered harmful. The levels found did not exceed trace

amounts that would be unavoidable even under conditions of good manufacturing practice, given background levels in the environment.

Has FDA published tolerance levels for lead in lipstick?

FDA has not published tolerance levels for contaminants, such as lead, in cosmetics. However, FDA does set specifications for impurities, such as lead, for color additives used in cosmetics. In addition, as noted above, cosmetics must by law be safe when used as directed in the labeling or under customary conditions of use.

It's been reported that levels of lead in certain lipstick exceed those for candy. Is this a fair comparison?

FDA has yet to confirm the latest reports. However, it is not valid to compare the FDA-recommended level for lead in candy, a product intended for ingestion and which may be consumed on a regular basis, with lead levels in lipstick, a product intended for topical use and which is ingested in much smaller quantities than candy.

Is FDA following up on the latest reports?

Because allegations regarding lead in lipstick surface periodically, and because of the amount of time since FDA last surveyed lipsticks in the marketplace, FDA has decided to allocate the resources necessary to conduct independent testing of a selection of lipstick on the market. FDA has obtained commercial samples of the same lipstick brands cited in the recent report. FDA laboratories have been adapting a previously validated, state-of-the-art method to do the analyses.

Does FDA intend to take enforcement action, given the latest report?

As a science-based public health agency, FDA bases its actions upon authoritative scientific evidence and the agency's authority under the law. FDA takes seriously its commitment to develop and implement policies that will promote consumer safety and enhance public health. If FDA determines that a health hazard exists, the agency will advise the industry and the public, and will consider its options under the authority of the FD&C Act in protecting the health and welfare of consumers.

Cosmetics

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December 2005

The latest version of this guidance issued in November 2006. Below is an earlier version.

Guidance for Industry

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

Draft Guidance

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 75 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number 2005D-0481.

For questions regarding this draft document, contact Michael E. Kashtock at (301) 436-2022.

*Additional copies are available from:
Office of Plant and Dairy Foods
Division of Plant Product Safety HFS-305
Center for Food Safety and Applied Nutrition
Food and Drug Administration, 5100 Paint Branch Parkway
College Park, MD 20740
<http://www.cfsan.fda.gov/guidance.html>*

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
December 2005

Guidance for Industry ^[1]

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

Draft Guidance

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternate approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This guidance provides a recommended maximum lead level in candy^[2] likely to be consumed frequently by small children. FDA considers the recommended maximum lead level to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients and to be protective of human health. For additional discussion of the background and rationale underlying this recommended level, see draft "Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children."

In addition to announcing the recommended maximum lead level, FDA is rescinding the previous .5 ppm guideline for considering enforcement action against candy products likely to be consumed frequently by small children. Further, FDA is reiterating its enforcement policy toward the use of lead-based ink on candy wrappers as originally stated in its 1995 letter to the industry on this subject.

FDA considers the issuance of this guidance to be a prudent public health measure consistent with the Agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or

recommended, but not required.

II. Discussion

A. Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA is recommending that lead levels in candy products likely to be consumed frequently by small children not exceed 0.1 ppm because such levels are achievable under good manufacturing practices and would not pose a significant risk to small children for adverse effects. This recommended maximum level of 0.1 ppm for lead in candy likely to be consumed frequently by small children is consistent with the FDA's longstanding goal of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained. This recommendation is further discussed in the supporting document for this guidance noted above.

B. Enforcement Policy for Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA is rescinding the guidance it provided in the 1995 letter that stated that, where frequent consumption of candy products by small children could be anticipated, FDA would consider taking regulatory action against candy with lead levels that exceed 0.5 ppm.

The 0.1 ppm recommended maximum lead level is not an enforcement guideline. FDA intends to consider several factors in bringing enforcement actions regarding lead in candy likely to be consumed frequently by small children, including the level of lead present and the best available consumption data.

C. Enforcement Policy for Use of Lead-Based Inks on Candy Wrappers

FDA is reiterating in this guidance that FDA's policy toward the use of lead-based ink on candy wrappers remains as stated in its 1995 letter to the industry on this subject.

Generally speaking, if lead derived from a lead-based printing ink is found on the portion of the package that directly contacts food or, if such lead could be expected to migrate into the packaged food, the product would likely be regarded as being in violation of the Federal Food, Drug, and Cosmetic Act. Use of the printing ink only on the outer (non-food contact) surface of the package does not ensure that it will not contaminate the food.

Suitable non-lead-based printing inks are widely available for use in food packaging, and we continue to strongly urge all candy manufacturers, including those whose products are offered for import into this country, to refrain from the use of lead-based printing inks on their packaging materials.

In addition, the use of lead-based printing inks on candy wrappers may subject a firm to regulatory action by the U.S. Consumer Product Safety Commission under the Federal Hazardous Substances Act (see CPSC letters to US candy importers ([PDF](#)) and candy producers

in Mexico ([PDF](#)) for additional information).

[1] This guidance has been prepared by the Office of Plant and Dairy Foods in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

[2] We have included within the broad category of Mexican style candy, powdered snack mix products, which are generally made in Mexico and typically contain combinations of salt, chili powder, sugar and flavoring. These products, popular with children and adults, may be sold alongside of candy in retail outlets, and can be consumed directly from the container like candy, as well as being sprinkled onto fruits and vegetables or in beverages.

Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children December 2005

Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers June 13, 1995

Consumer Product Safety Commission: Letter to U.S. Candy Importers (available in [PDF](#)) July 9, 2004

Consumer Product Safety Commission: Letter to Candy Producers in Mexico (available in [PDF](#)) July 12, 2004

FDA Proposes New Guidance to Further Reduce Children's Risk From Lead Exposure in Certain Candy December 22, 2005

The latest version of this guidance issued in November 2006. Above is an earlier version.

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